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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/040,103 03/17/98 MASON J 52494-21

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HM22/0806

EXAMINER

GUZO, D

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

08/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/040,103	Applicant(s) MASON, JAMES M.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-11,13-40 and 42-70 is/are pending in the application.
- 4a) Of the above claim(s) 22-35,39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-11,13-21,36-38,42-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Zeta Davis

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 22-35 and 39-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10. Applicants requested cancellation of these claims in the After Final Amendment filed 9/25/00; however, since the After Final amendment was not entered (See Advisory Action mailed 10/24/00) and applicants have not requested entry of said After Final Amendment in the RCE request, the non-elected claims are still pending. It is also noted that applicants' amendment to claim 1 is predicated upon the non-entry of the After Final Amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8-11, 13-21, 36-38 and 42-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Applicants recite in claims 1, 48, 53, 58 and 63 the limitation that the "...cell line exhibits substantially no hybridization to a Moloney-MLV retrovirus gag, pol, and/or env probe...". However, the instant specification only supports use of a Moloney-MLV gag-

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pol probe. Use of Moloney—MLV gag probes, pol probes or env probes or combinations of gag and env, pol and env, etc. are therefore not supported by the specification, as filed.

Applicants recite, in claims 3 and 46, a cell line that expresses "...galactose α (1,3) galactosyl epitopes and is not treated to reduce such expression." However, support for the negative limitation that the cell lines are not treated to reduce expression of the galactose α (1,3) galactosyl epitopes is lacking in the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 8-11, 13-21, 36-38, 42-45, 48, 53, 58 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 48, 53, 58, 63 (and dependent claims) are vague in the recitation of the phrase "...exhibits substantially no hybridization to a Moloney-MLV retrovirus gag, pol, and/or env probe under stringent hybridization conditions...". This rejection is maintained for reasons of record in the previous Office Actions (Papers 11 and 15). Applicants' traverse of this rejection recites arguments which the examiner has previously addressed (See Office Action, Paper #15, pp. 5-7). The examiner notes that the specification offers no guidance in interpreting the metes and bounds of the term "substantially no hybridization" under "stringent washing conditions". It is again noted that applicants recite a subjective term "substantially no hybridization" with no frame of

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reference which is based upon another subjective term "under stringent washing conditions" that can vary depending upon who is defining the stringency of the washing conditions.

Claim 20 (and dependent claims) are vague in that claim 20 depends from cancelled claim 12.

Miscellaneous notes:

In Claim 50, the word "produced" is misspelled as "produed".

In Claim 51, line 5, the word "or" should be "of".

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Robert Schwartzman, can be reached on (703) 308-7307. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

David Guzo
August 1, 2001

DAVID GUZO
PRIMARY EXAMINER
